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**Patent and Trademark Office**  
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/450,641	05/25/95	KOLEN P	07367/002001

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33M1/1201

EXAMINER	
NASSER, R	
ART UNIT	PAPER NUMBER
3311	19

DATE MAILED: 12/01/97

**Please find below a communication from the EXAMINER in charge of this application.**

Commissioner of Patents

# Office Action Summary

Application No.  
**08/450,641**

Applicant(s)  
**Kolen et al**

Examiner  
**Robert Nasser**

Group Art Unit  
**3311**



☒ Responsive to communication(s) filed on paper #17, filed 9/2/1997

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 8-18 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 8-18 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 18

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10 and 13 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. The facts stated in the information disclosure statement, including the description in figure 7 of copending application 08/700290, regarding the prototype are sufficient to establish that the invention described in these claims was on sale more than one year prior to the filing date.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elkins et al in view of Fletcher et al. Elkins et al shows all of the features of claim 8 except that the control of the mixing of the fluids is done manually, not automatically. However, Fletcher et al is select from a myriad of references that teach that temperature control in such thermal systems may be provided electronically, to eliminate the inaccuracies of human measurement. Hence, it would have been obvious to modify Elkins et al to include electronic control, to eliminate human error. Claim 9 is rejected in that the combination mixes a predetermined volume of fluid.

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Claim 10 is rejected in that Elkins allows for changes in the rate of flow of the device, which also changes the pressure. Claim 11 is rejected in that, as such, the pressure varies, providing tactile stimulation. Claim 13 is rejected in that it is inherent that the combination has a temperature sensor so as to control the operation of valve 50 in mixing the fluids.

Claims 12 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over as applied to claims 8-11 and 13 above, and further in view of French et al. Claims 12, 17, and 18 are rejected in that French teaches shutting the system down when the fluid level is too low, to prevent injury to the patient. From this teaching, it would have been obvious to modify the above combination to include such a safety feature, to prevent patient injury. The examiner notes that it would have been within the ability of one skilled in the art to also sound an alarm, to alert the user of the problem. The specifics of the circuitry would have been obvious to one skilled in the art. Claims 14-16 are rejected in that French further allows the user to set the desired temperature, which would result in a constant time-temperature profile. This allows the user, patient or doctor, to set the device to account for individual patient needs. Hence, it would have been obvious to modify the above combination to use such temperature setting means, to conform the device to the individual user. The combination then operates as claimed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Mahawili patents show a similar invention to applicant's. In fact the '220 patent reads on at least claim 8. However, the filing date of the '200 patent is one day after applicant's.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser Jr. whose telephone number is (703) 308-3251. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 to 6:00.

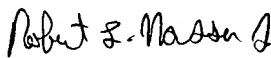
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Bahr, can be reached on (703) 308-1066. The fax phone number for this Group is (703) 308-3139.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [jennifer.bahr@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

RLN  
November 23, 1997

  
**ROBERT L. NASSER  
PRIMARY EXAMINER**